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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/933,115 | 08/20/2001 | Paul B. Fisher | A34466 (070050.1618) | 7088 |
| 21003 | 7590 | 10/06/2003 | EXAMINER | |
| BAKER & BOTTS | | | ANGELL, JON E | |
| 30 ROCKEFELLER PLAZA | | | ART UNIT | |
| NEW YORK, NY 10112 | | | PAPER NUMBER | |

1635

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/933,115

Applicant(s)

FISHER, PAUL B.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-4, 12-14, 22-24, 32-34 drawn to a method for inhibiting proliferation and inducing cell death in a population of cancer cells by increasing the amount of differentiation associated protein MDA-7 using a nucleic acid encoding MDA-7, and decreasing RAS activity within the population, classified in class 514, subclass 44.

Upon election of Group I further Group election of one of the following patentably distinct subgroups is also required:

- A) antisense molecule (claim 42)
- B) ribozyme
- C) precursor of a triple helix
- D) a farnesyl transferase inhibitor

Upon election of any subgroups A-D above, further Group election of one of the following patentably distinct subgroups is also required:

- i) an agent which inhibits EGF receptor (claims 10, 20, 30, 40)
- ii) an agent which inhibits MAP kinase (claims 10, 20, 30, 40)
- iii) an agent which inhibits MAPK kinase (claims 10, 20, 30, 40)
- iv) an agent which inhibits PI3 kinase (claims 10, 20, 30, 40)

Claims 1, 11, 21, 31 and 41 link(s) the inventions of Groups I:A-D and i-iv; Claims 5, 15, 25 and 35 link(s) the inventions of Groups I:A-D; claims 6-9, 16-19, 26-29, and 36-39 link(s) inventions I:A and i-iv. The restriction requirement between the linked inventions is subject to

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the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

- II. Claims 43 and 44, drawn to a method for identifying candidate cancer cells for treatment, classified in class 435, subclass 6.
- III. Claim 45, drawn to a viral vector comprising a nucleic acid encoding MDA-7 protein and a nucleic acid encoding an antisense ras nucleic acid, classified in class 435, subclass 320.1
- IV. Claim 47, drawn to a method for inhibiting the proliferation of a cancer cell by introducing isolated MDA-7 protein, classified in class 514, subclass 12.

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- V. Claim 48-50, drawn to a method for inhibiting the proliferation of a cancer cell by introducing a nucleic acid encoding MDA-7 protein which gets secreted, classified in class 514, subclass 44.

Claim 46 link(s) the inventions of Groups IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

In order to be perfectly clear, if Group I is elected, then election of one (1) of A-D is required AND further election of one (1) of i-iv is also required.

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The inventions are distinct, each from the other because of the following reasons:

2. The Inventions set forth as subgroups A-D are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case although each of the agents of A-D are inhibitory agents, they have different modes of operation. For instance, antisense molecules are complementary to mRNA and form a double stranded complex with target mRNA inhibiting gene expression, ribozymes are catalytic molecules, triplex forming precursors target double stranded nucleic acid and form a triplex structure with the target nucleic acid, and farnesyl transferase inhibitors inhibit the farnesyl transferase enzyme. Each of these compounds have different modes of operation. Therefore, they are patentably distinct and restriction is proper.

3. The Inventions set forth as subgroups i-iv are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case subgroups i-iv are unrelated because each is drawn to an agent which inhibits a different target molecule, such as EGF-receptor, MAP kinase, MAPK kinase, and PI3 kinase. Therefore, the different subgroups they have different modes of operation, different functions, or different effects, and restriction is proper.

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4. Inventions III is related inventions I (including A-D and i-iv), II, IV and V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of using the vector can be practiced with another materially different product, such as two different nucleic acids wherein one nucleic acid operably encodes MDA-7 protein and the other nucleic acid operably encodes the antisense molecule. Furthermore, the vector of Group III can be used in a materially different process of use, such as expressing MDA-7 in a host cell for purification purposes, or to use the vector encoding MDA-7 as a template for PCR reactions for amplifying the sequence encoding MDA-7 for cloning into different expression vectors.

5. Inventions I (including A-D and i-iv), II, IV and V are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods utilize different materials, have different method steps, or have different desired effects; indicating that different inventions have different modes of operation, different functions, or different effects. Therefore, restriction is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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7. Because these inventions are distinct for the reasons given above and the search required for each Group is distinct (i.e. not coextensive with the searches of the other Groups), restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
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DAVE T. NGUYEN
PRIMARY EXAMINER